EMEA/H/C/002318

EPAR summary for the public

Repaglinide Accord

repaglinide

This is a summary of the European public assessment report (EPAR) for Repaglinide Accord. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Repaglinide Accord.

What is Repaglinide Accord?

Repaglinide Accord is a medicine that contains the active substance repaglinide. It is available as round tablets (0.5 mg, 1 mg and 2 mg).

Repaglinide Accord is a 'generic medicine'. This means that Repaglinide Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called NovoNorm. For more information on generic medicines, see the question-and-answer document here.

What is Repaglinide Accord used for?

Repaglinide Accord is used in patients who have type 2 diabetes (non-insulin-dependent diabetes). It is used together with diet and exercise to lower blood glucose (sugar) levels in patients whose hyperglycaemia (high blood glucose levels) cannot be controlled by diet, weight reduction and exercise. Repaglinide Accord may also be used with metformin (another anti-diabetes medicine) in type 2 diabetes patients whose blood glucose levels are not satisfactorily controlled on metformin alone.

The medicine can only be obtained with a prescription.

How is Repaglinide Accord used?

Repaglinide Accord is taken before meals, normally up to 15 minutes before each main meal. The dose is adjusted to give the best control. A doctor should regularly test the patient's blood glucose to find the lowest effective dose. Repaglinide Accord can also be used for type 2 diabetes patients whose

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

© European Medicines Agency, 2012. Reproduction is authorised provided the source is acknowledged.

blood glucose levels are usually controlled well on diet, but are experiencing temporary loss of blood glucose control.

The recommended starting dose is 0.5 mg. This dose may need to be increased after one or two weeks.

If patients are transferred from another anti-diabetes medicine, the recommended starting dose is 1 mg.

Repaglinide Accord is not recommended for patients below 18 years of age because of a lack of information on safety and effectiveness in this age group.

How does Repaglinide Accord work?

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. Repaglinide Accord helps the pancreas to produce more insulin at mealtimes and is used to control type 2 diabetes.

How has Repaglinide Accord been studied?

Because Repaglinide Accord is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Repaglinide Accord?

Because Repaglinide Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Repaglinide Accord been approved?

The CHMP concluded that, in accordance with EU requirements, Repaglinide Accord has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the CHMP's view was that, as for NovoNorm, the benefit outweighs the identified risk. The Committee recommended that Repaglinide Accord be given marketing authorisation.

Other information about Repaglinide Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Repaglinide Accord on 22 December 2011.

The full EPAR for Repaglinide Accord can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Repaglinide Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 11-2011.